

NOV 30 2020

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLEClerk, U. S. District Court
Eastern District of Tennessee
At GreenevilleUNITED STATES OF AMERICA)
)
 v.)
)
 ARUN KAPOOR)No. 2:20-cr-11DJudge: Greer/Wyrick**PLEA AGREEMENT**

The United States of America, by the United States Attorney for the Eastern District of Tennessee ("USATNE"), the United States Department of Justice, Consumer Protection Branch ("USDOJ-CPB"), the defendant, ARUN KAPOOR, and the defendant's attorney, Oliver Benton Curtis III, have agreed upon the following:

1. The defendant will waive indictment and arraignment and plead guilty to an information charging the defendant with the following offenses:

(a) Count One – Introduction of Misbranded Drugs into Interstate Commerce with the Intent to Defraud and Mislead: The defendant, with the intent to defraud and mislead, introduced, delivered, and caused to be introduced and delivered, into interstate commerce from Florida to the Eastern District of Tennessee, Cifrazol 3,775-1mg cap (69336-0310-30), a drug that was misbranded in that its labeling was false and misleading in any particular, all in violation of 21 U.S.C. §§ 331(a), 352(a)(1), and 333(a)(2). The maximum punishment for this offense is three (3) years' imprisonment, a \$10,000 fine, one (1) year supervised release, and a \$100 mandatory assessment.

2. In consideration of the defendant's guilty plea:

(a) USATNE agrees not to further prosecute the defendant in the Eastern District of Tennessee for any other non-tax criminal offenses committed by the defendant that are

related to the charges contained in the information in this case and that are known to USATNE at the time this plea agreement is signed by both parties.

(b) USDOJ-CPB agrees not to further prosecute the defendant in any district in the United States for any other non-tax criminal offenses committed by the defendant that are related to the charges contained in the information in this case and that are known to USDOJ-CPB at the time this plea agreement is signed by both parties.

3. The defendant has read the information, discussed the charge and possible defenses with his defense counsel, and understands the crime charged.

4. In support of the defendant's guilty plea, USATNE, USDOJ-CPB, and the defendant agree and stipulate to the following facts, which satisfy the offense elements. These are the facts submitted for purposes of the defendant's guilty plea. They do not necessarily constitute all of the facts in the case. Other facts may be relevant to sentencing. The defendant, USATNE, and USDOJ-CPB retain the right to present additional facts to the Court to ensure a fair and appropriate sentence in this case.

(a) From no later than in or around the summer of 2015 through on or about April 1, 2018, the defendant misbranded prescription drugs and distributed, and caused them to be distributed, in interstate commerce, including by being mailed from other states to the Eastern District of Tennessee, in furtherance of a conspiracy to knowingly and intentionally defraud health care benefit programs.

(b) As further explained herein, the defendant knowingly and intentionally caused misbranded drugs to be dispensed in interstate commerce in furtherance of a conspiracy with, among others, Larry Everett Smith ("Smith"), ULD Wholesale Group ("ULD"), Mihir Taneja ("Taneja"), and Sterling Knight Pharmaceuticals LLC ("Sterling Knight").

(c) As further explained herein, the defendant knew and intended that this scheme to dispense misbranded prescription drugs in interstate commerce entailed: (i) repackaging non-prescription vitamins as though they were prescription drugs; (ii) making fraudulent misrepresentations to the Food and Drug Administration ("FDA"); (iii) making fraudulent misrepresentations to Medispan and First Databank; (iv) mailing misbranded prescription drugs and vitamin products disguised as prescriptions drugs; and (v) submitting fraudulent claims for payments for those misbranded prescriptions to health care benefit programs.

(d) The deceived health care benefit programs include the pharmacy benefit managers ("PBMs") CVS Caremark, Express Scripts, MedImpact, Prime Therapeutics, and others.

(e) During the time period of this conspiracy, the defendant, together with Taneja, owned and operated Sterling Knight as a "virtual manufacturer" to label and distribute prescription drugs and other products manufactured by third parties.

(f) Among other products, the defendant and Taneja used Sterling Knight to label and package several products, including Fenortho 200 mg capsules (NDC: 69336-0113-10), Lidopril (NDC: 69336-0825-01), Lidopril XR (NDC: 69336-0826-01), Lidocaine 5% (NDC: 69336-0103-35), Durachol (69336-03-0030), and Cifrazol (69336-03-1030).

(g) Fenortho, Lidopril, Lidopril XR, and Lidocaine were all prescription "drugs" as that term is defined in 21 U.S.C. § 321(g)(1). In particular, they were (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; or (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (C) articles (other than food) intended to affect the structure or any function of

the body of man or other animals; or (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

(h) Durachol and Cifrazol were not prescription drugs, but were instead non-prescription vitamin capsules containing 1 mg of folic acid and 3,775 units of Vitamin D. The defendant, Taneja, and Sterling Knight bought millions of these vitamin capsules from a manufacturer that was not licensed by the FDA to manufacture drugs.

(i) The defendant and Taneja then repackaged these non-prescription vitamins as prescription-only drugs, assigned them a national drug code ("NDC"), branded them with the Sterling Knight label and the brand names "Durachol" and "Cifrazol", and bottled them in 30-count bottles, with the intent to sell them to wholesalers and pharmacies as though they were prescription drugs, knowing that those pharmacies would then bill them to PBMs as though they were prescription drugs.

(j) The defendant and Taneja fraudulently registered Durachol and Cifrazol as prescription drugs with the FDA, First Databank, and Medispan, even though they knew that these products were not prescription drugs. Doing this was essential in order to increase the likelihood that the PBMs would pay for them.

(k) The defendant and Taneja then used Sterling Knight to sell thousands of bottles of Durachol and Cifrazol to Smith and his wholesaler, ULD, knowing that Smith would dispense them to patients throughout the United States, including in the Eastern District of Tennessee.

(l) The defendant and Taneja agreed that they would supply Smith with Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol so that he had a product to dispense to the patients and bill to the PBMs. The defendant and Taneja caused Sterling Knight to

sell Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol to Smith's company, ULD, knowing that Smith then mailed these products from Alpha-Omega, Germaine, and Zoetic to patients throughout the United States.

(m) The defendant knew that Smith, through Tanith, caused Alpha-Omega, Germaine, and Zoetic to fraudulently bill the PBMs for the prescriptions for Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol.

(n) The defendant, Taneja, Sterling Knight, and Smith also knew that when billing the PBMs for prescriptions, Alpha-Omega, Germaine, and Zoetic were required to collect patient copays, and that if they weren't able to do so, the PBMs would terminate those pharmacies' ability to bill for prescriptions. However, the defendant, Taneja, Sterling Knight, and Smith also knew that the patients would not actually pay the copays.

(o) To address this problem, the defendant and Taneja agreed with Smith to make it appear as though Sterling Knight paid a "manufacturers' coupon" for the full amount of each patient copay for the thousands of prescriptions. The defendant and Taneja caused Sterling Knight to establish a relationship with a third-party manufacturers' coupon rebate facilitator called AlphaScrip. AlphaScrip was already in the business of processing legitimate manufacturers' coupons on behalf of pharmaceutical manufacturers and paying the proceeds obtained from the manufacturers to pharmacies that were able to submit the manufacturers' coupon.

(p) In a *bona fide* manufacturers' coupon: (i) the patients bring the coupon to the pharmacy, having obtained it directly from a doctor or the manufacturer; (ii) the pharmacy submits an electronic claim to AlphaScrip with the presented coupon code; (iii) AlphaScrip cross-references the coupon code with its list of enrolled pharmaceutical manufacturers to determine how much to pay the pharmacy for the copay coupon; (iv) AlphaScrip then pays the coupon

amount to the pharmacy with a remittance indicating that the payment is for the patients' copay; and (v) AlphaScrip then collects that copay coupon amount from the manufacturer, which bears the economic cost of the copay coupon.

(q) In this situation, however, Smith, not the manufacturer (Sterling Knight), funded the entirety of the copay coupon.

(r) The defendant and Taneja provided Sterling Knight's Alpha-Scrip coupon code directly to Smith who, in turn, caused Alpha-Omega, Germaine, and Zoetic to submit claims for the manufacturers' coupon to AlphaScrip for essentially every single prescription purchased.. AlphaScrip processed those coupons, obtained reimbursement from Sterling Knight, and paid the resulting amount to the submitting pharmacy – Alpha-Omega, Germaine, and Zoetic.

(s) But, although Sterling Knight sent money to AlphaScrip, it didn't actually bear the economic cost of that payment. Instead, the defendant and Taneja, upon receiving invoices from Alpha-Scrip, simply forwarded those invoices to Smith and told him to pay them, which Smith did using the money he extracted from Alpha-Omega, Germaine, and Zoetic's bank accounts.

(t) Thus, the defendant and Taneja caused Sterling Knight to help Smith collect money from Smith's pharmacies, through Sterling Knight and AlphaScrip, and then direct it *back* to those same pharmacies, all for the purpose of obtaining the remittance indicating that the patients' copays had been paid, which was false. This was done for the purpose of deceiving the PBMs into believing that the patients copays had been paid, which was false.

(u) From the summer of 2016 through the end of 2017, the defendant and Taneja, through Sterling Knight, continued to sell Fenortho, Lidopril, Lidopril XR, Lidocaine,

Durachol, and Cifrazol to Smith, knowing and intending that these products would be dispensed to patients throughout the United States.

(v) In particular, on or about September 19, 2017, the defendant, Taneja, Sterling Knight, and Smith, with the intent to defraud and mislead, introduced, delivered, and caused to be introduced and delivered, into interstate commerce from Florida to patient B.N. in the Eastern District of Tennessee, Cifrazol 3,775-1mg cap (NDC: 69336-1310-30), a drug that was misbranded in that its labeling was false and misleading in any particular (including, without limitation, in that it stated falsely that the product could only be taken pursuant to a prescription), which Alpha-Omega billed fraudulently to CVS Caremark and for which CVS Caremark paid Alpha-Omega \$1,464.

(w) The defendant, together with Taneja, also caused Sterling Knight to sell Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol and other products to Synergy.

(x) The defendant understood that health care benefit programs, as defined by 18 U.S.C. § 24(b), would reimburse for prescriptions pursuant to this scheme. Private insurance companies and self-insured groups are health care benefit programs. However, the defendant intended that no “federal health care program,” as defined by 42 U.S.C. § 1320a-7b(f), would reimburse for Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol or other Sterling Knight products. Because the defendant knew that the federal government imposed stricter regulatory requirements and had greater oversight than private health care benefit programs, the defendant went to lengths to ensure that no representations or claims were made to federal health care programs by himself, Sterling Knight, Alpha-Omega, Germaine, or Zoetic in connection with this scheme. In reality, federal health care programs made only modest and insubstantial payments to Alpha-Omega, Germaine, and Zoetic for Sterling-Knight products as part of this scheme.

USATNE and USDOJ-CPB are unaware of any statements or claims made by the defendant or Sterling Knight to any federal health care program in connection with this scheme. The defendant does not have any knowledge as to whether or not Andrew Assad, Peter Bolos, Michael Palso, Synergy, or Precision took any steps to prevent claims from being submitted to federal health care benefit programs as part of this scheme.

(y) As a result of billing the PBMs for misbranded drugs, the defendant and his co-conspirators caused an actual loss to the PBMs in the amount of \$20,981,786. This is the full amount that the PBMs paid to all pharmacies for invalid prescriptions for products manufactured or distributed by the defendant's company, Sterling Knight.

(z) The defendant knew that had the PBMs not been defrauded in the various ways described in this plea agreement, they would not have paid for claims for payment submitted by the pharmacies, for products that had been misbranded and fraudulently packaged as prescription drugs, and dispensed to patients who were deceived into providing their insurance information and who didn't want such products in the first place.

5. The defendant is pleading guilty because the defendant is in fact guilty. The defendant understands that, by pleading guilty, the defendant is giving up several rights, including:

- (a) the right to have his case presented to a grand jury for these crimes;
- (b) the right to plead not guilty;
- (c) the right to a speedy and public trial by jury;
- (d) the right to assistance of counsel at trial;
- (e) the right to be presumed innocent and to have the burden of proof placed on the United States to prove the defendant guilty beyond a reasonable doubt;
- (f) the right to confront and cross-examine witnesses against the defendant;

(g) the right to testify on one's own behalf, to present evidence in opposition to the charges, and to compel the attendance of witnesses; and

(h) the right not to testify and to have that choice not used against the defendant.

6. The parties agree that the appropriate disposition of this case would be the following as to Count One:

(a) The Court may impose any lawful term of imprisonment, any lawful fine, and any lawful term of supervised release up to the statutory maximum.

(b) The Court will impose special assessment fees as required by law; and

(c) The Court may order forfeiture as applicable and restitution as appropriate (see paragraph 9).

(d) No promises have been made by any representative of USATNE or USDOJ-CPB to the defendant as to what the sentence will be in this case. Any estimates or predictions made to the defendant by defense counsel or any other person regarding any potential sentence in this case are not binding on the Court, and may not be used as a basis to rescind this agreement or withdraw the defendant's guilty plea. The defendant understands that the sentence in this case will be determined by the Court after it receives the presentence investigation report from the United States Probation Office and any information presented by the parties. The defendant acknowledges that the sentencing determination will be based upon the entire scope of the defendant's criminal conduct, the defendant's criminal history, and pursuant to other factors and guidelines as set forth in the Sentencing Guidelines and the factors set forth in 18 U.S.C. § 3553.

7. Given the defendant's agreement to plead guilty, USATNE and USDOJ-CPB will not oppose a two-level reduction for acceptance of responsibility under the provisions of § 3E1.1(a) of the Sentencing Guidelines. Further, if the defendant's offense level is 16 or greater,

and the defendant is awarded the two-level reduction pursuant to § 3E1.1(a), USATNE and USDOJ-CPB agree, at or before the time of sentencing, to move the Court to decrease the offense level by one additional level pursuant to § 3E1.1(b) of the Sentencing Guidelines. Should the defendant engage in any conduct or make any statements that are inconsistent with accepting responsibility for the defendant's offense, including violations of conditions of release or the commission of any additional offense(s) prior to sentencing, USATNE and USDOJ-CPB will be free to decline to make such motion, to withdraw that motion if already made, and to recommend to the Court that the defendant not receive any reduction for acceptance of responsibility under § 3E1.1 of the Sentencing Guidelines.

8. The defendant agrees to pay the special assessment in this case prior to sentencing.

9. The defendant agrees that the Court shall order restitution, pursuant to any applicable provision of law, for any loss caused to: (1) the victims of any offense charged in this case; and (2) the victims of any criminal activity that was part of the same course of conduct or common scheme or plan as the defendant's charged offense. Pursuant to Rule 11(c)(1)(B) of the Federal Rules of Criminal Procedure, the parties agree to recommend that the defendant be responsible, jointly and severally with Sterling Knight and Mihir Taneja, for restitution in the amount of \$20,981,786, which is the full amount that the PBMs paid to all pharmacies for invalid prescriptions for products manufactured or distributed by the defendant's company, Sterling Knight.. The proposed restitution amounts described in this paragraph correspond to actual losses sustained by the health care benefit programs and their agents, the PBMs, as a result of the defendant's actions described in this plea agreement.

10. The defendant agrees to pay all fines and restitution imposed by the Court to the Clerk of Court. The defendant also agrees that the full fine and/or restitution amount(s) shall be

considered due and payable immediately. Notwithstanding any provision of this agreement to the contrary, the defendant agrees to pay, or to cause Sterling Knight to pay, the full amount of restitution to the Court, at or before sentencing. If the defendant cannot pay the full amount immediately and is placed in custody or under the supervision of the Probation Office at any time, the defendant agrees that the Bureau of Prisons and the Probation Office will have the authority to establish payment schedules to ensure payment of the fine and/or restitution. The defendant further agrees to cooperate fully in efforts to collect any financial obligation imposed by the Court by set-off of federal payments, execution on non-exempt property, and any other means the United States deems appropriate. The defendant and counsel also agree that the defendant may be contacted post-judgment regarding the collection of any financial obligation imposed by the Court without notifying the defendant's counsel and outside the presence of the defendant's counsel. In order to facilitate the collection of financial obligations to be imposed with this prosecution, the defendant agrees to disclose fully all assets in which the defendant has any interest or over which the defendant exercises control, directly or indirectly, including those held by a spouse, nominee, or other third party. In the event that the defendant fails to fulfill any financial obligation under this agreement in a timely fashion, the defendant additionally agrees to the following specific terms and conditions:

(a) If so requested by USATNE or USDOJ-CPB, the defendant will promptly submit a completed financial statement to USATNE and USDOJ-CPB, in a form it or they provide and as it or they direct. The defendant promises that such financial statement and disclosures will be complete, accurate, and truthful.

Defendant's Initials 

(b) The defendant expressly authorizes USATNE and USDOJ-CPB to obtain a credit report on the defendant in order to evaluate the defendant's ability to satisfy any financial obligation imposed by the Court.

(c) If so requested by USATNE or USDOJ-CPB, the defendant will promptly execute authorizations on forms provided by USATNE and USDOJ-CPB to permit USATNE and USDOJ-CPB to obtain financial and tax records of the defendant.

11. The defendant acknowledges that the principal benefits to USATNE and USDOJ-CPB of this agreement include the conservation of limited government resources and bringing a certain end to the case. Accordingly, in consideration of the concessions made by USATNE and USDOJ-CPB in this agreement and as a further demonstration of the defendant's acceptance of responsibility for the offense committed, the defendant voluntarily, knowingly, and intentionally agrees to the following:

(a) The defendant will not file a direct appeal of the defendant's conviction or sentence with one exception: The defendant retains the right to appeal a sentence imposed above the sentencing guideline range determined by the Court or above any mandatory minimum sentence deemed applicable by the Court, whichever is greater. The defendant also waives the right to appeal the Court's determination as to whether the defendant's sentence will be consecutive or partially concurrent to any other sentence.

(b) The defendant will not file any motions or pleadings pursuant to 28 U.S.C. § 2255 or otherwise collaterally attack the defendant's conviction or sentence, with two exceptions: The defendant retains the right to file a § 2255 motion as to (i) prosecutorial misconduct and (ii) ineffective assistance of counsel.

(c) The defendant will not, whether directly or by a representative, request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

12. This plea agreement becomes effective once it is signed by the parties and is not contingent on the defendant's entry of a guilty plea. The defendant's signature on this plea agreement constitutes the defendant's admission that the facts contained herein are true and accurate. If USATNE or USDOJ-CPB violate the terms of this agreement, the defendant will have the right to withdraw from this agreement. If the defendant violates the terms of this agreement in any way (including, without limitation, by failing to enter a guilty plea as agreed herein, moving to withdraw guilty plea after entry, or by violating any court order or any local, state, or federal law pending the resolution of this case), then USATNE or USDOJ-CPB will have the right to void any or all parts of the agreement and may also enforce whatever parts of the agreement it chooses. In addition, USATNE or USDOJ-CPB may prosecute the defendant for any and all federal crimes that the defendant committed related to this case, including any charges that were dismissed and any other charges that USATNE and USDOJ-CPB agreed not to pursue. The defendant expressly waives any statute of limitations defense and any constitutional or speedy trial or double jeopardy defense to prosecution for the conduct contemplated by this agreement. The defendant also understands and agrees that a violation of this agreement by the defendant does not entitle the defendant to withdraw the defendant's guilty plea in this case.

13. The United States will file a supplement in this case, as required in every case by the Local Rules of the United States District Court for the Eastern District of Tennessee, even

though there may or may not be any additional terms. If additional terms are included in the supplement, they are hereby fully incorporated herein.

14. This plea agreement and supplement constitute the full and complete agreement and understanding between the parties concerning the defendant's guilty plea to the above-referenced charges, and there are no other agreements, promises, undertakings, or understandings between the defendant and the United States. The parties understand and agree that the terms of this agreement can be modified only in writing signed by all of the parties and that any and all other promises, representations, and statements whether made before, contemporaneous with, or after this agreement, are null and void.

* * * * *

J. DOUGLAS OVERBEY
UNITED STATES ATTORNEY

For USATNE:

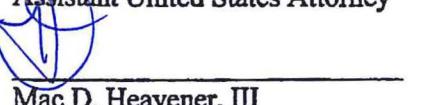
11/30/2020
Date

11/30/2020
Date

By:


Timothy C. Harker
Assistant United States Attorney

By:


Mac D. Heavener, III
Assistant United States Attorney

For USDOJ-CPB:

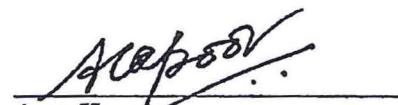
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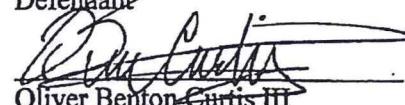

David L. Gunn
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch

For the Defendant:

11/25/2020
Date

11/29/20
Date


Arun Kapoor
Defendant


Oliver Benton-Curtis III
Attorney for the Defendant